

REMARKS

Status of the Claims

Claims 1, 4, 5, 10, 12, 13 and 15-22 are currently pending in the application. Claims 1, 3-5, 9, 10, 12, 13 and 15-22 stand rejected. Claim 1 has been amended as set forth herein. Claims 3 and 9 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is supported by original claims 3 and 9. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3-5, 10, 12, 15-18 and 21 stand rejected under 35 U.S.C. § 103(a) as being obvious in light of Woodard et al., EP 0512767 (hereinafter, "Woodard et al."), and Morishita et al., U.S. Patent No. 4,118,336 (hereinafter, "Morishita et al."). (*See*, Office Action of November 1, 2006, at page 3, hereinafter, "Office Action").

Furthermore, claim 13 stands rejected under 35 U.S.C. § 103(a) as being obvious in light of Woodard et al., Morishita et al., Gjerde et al., U.S. Patent No. 6,056,877 (hereinafter, "Gjerde et al."), and Benjamin et al., U.S. Patent No. 5,695,946 (hereinafter, "Benjamin et al."). (*Id.* at page 7).

Additionally, claims 19 and 20 stand rejected under 35 U.S.C. § 103(a) as being obvious in light of Woodard et al., Morishita et al., Gjerde et al., and Heath et al., WO 99/13976 (hereinafter, "Heath et al."). (*Id.* at page 8).

Claims 3 and 9 have been cancelled herein without prejudice or disclaimer, thus obviating the rejections of these claims. Applicants traverse the rejections as to the remaining claims as hereinafter set forth.

In response to the Reply of May 22, 2006, the Examiner states that since Morishita et al. disclose saponification of cellulose acetate and since this cellulose acetate is inherently porous, Morishita et al. disclose selection of a surface saponification rate and pore size. (*Id.* at page 6). Furthermore, the Examiner states that the claims require only “selecting” a saponification rate and pore size and do not actually dictate which rate and size, respectively, should be selected. (*Id.*).

Applicants first point out that Morishita et al. disclose only the use of “beads” and that the Morishita et al. methods utilize a pore size of 10 to 80 Angstroms. This length corresponds to 1 to 8 nanometers or 0.001 to 0.008 micrometers. This range of pore size is well outside the pore size encompassed by the presently claimed invention of “0.1 μm to 10 μm ” as presently recited in amended claim 1.

It is noted that claim 9 is not rejected as being obvious in light of the cited references and that claim 1 has been amended to recite the limitations of claim 9.

Thus, at least for this reason, the present claims, as amended, are not obvious in light of the disclosure of any of the cited references, in combination with the disclosure of Morishita et al.

Applicants do not concede that the Examiner has established a *prima facie* case of obviousness. However, assuming *arguendo*, that the Examiner has established a *prima facie* case of obviousness, submitted herewith is a Declaration under 37 C.F.R. § 1.132 providing empirical

evidence of unexpected results (executed Declaration to follow). In this Declaration, the Example disclosed in Morishita et al. has been repeated and compared with the presently claimed invention. Applicants believe that the Declaration submitted herewith fully addresses the disclosure of Morishita et al. and shows evidence of unexpected results. Thus, Applicants have rebutted any alleged *prima facie* case of obviousness. The claims are believed to be non-obvious in light of the presently cited references because all of the Examiner's present rejections are at least in part dependent upon the disclosure of Morishita et al. Having substantially addressed the inadequacies of this reference, Applicants believe all claims to be in condition for allowance, at least as presently amended.

Therefore, reconsideration and withdrawal of the obviousness rejection of claims 1, 4, 5, 10, 12, 15-18 and 21 are respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 3-5, 9, 10, 12, 13 and 15-22 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (See, Office Action, at page 11). Claims 3 and 9 have been cancelled herein without prejudice or disclaimer, thus obviating the rejections of these claims. Applicants traverse the rejections as to the remaining claims as hereinafter set forth.

The Examiner states the claims lack enablement because, 1) the claims encompass any acetylcellulose film, 2) the claims encompass the separation of any sized nucleic acid from a solution containing any sized nucleic acids, and 3) too much experimentation is required because

the claims recite “selecting a rate of surface saponification and pore size.” (*Id.* at pages 11, 18 and 20, respectively).

As to the first point, Applicants note that although they do not agree the claims lack enablement, to expedite prosecution, claim 1 has been amended, without prejudice or disclaimer, to be directed to the use of only triacetylcellulose. The Examiner admits at page 11 of the Office Action that the present claims are enabled for separation of nucleic acids using surface saponified triacetylcellulose.

However, Applicants maintain that the ample evidence provided in the disclosure combined with the additional empirical evidence provided in the Declaration submitted with the prior Reply, are adequate to fully enable the claims as currently amended. That is, the Examiner has been provided with an overwhelming amount of evidence regarding the range and sizes of DNA that may be separated by the present invention. Thus, Applicants request reconsideration of the Examiner’s rejection.

Furthermore, the Examiner’s discussion of selection of a surface saponification rate fails to properly take into account the level of the person of ordinary skill in the art. That is, one of ordinary skill in the art would most certainly find it routine to determine the amount of saponification and/or pore size to use to achieve the presently claimed methods since the claims no longer encompass any unusually large or unusually small nucleic acid lengths. For instance, the Examiner’s attention is directed to claim 1, wherein it is clearly recited that, “the pore size of the porous film is 0.1 μm to 10 μm .” Thus, based at least on the Stokes radius of DNA, this limitation certainly precludes the separation of any sized DNA. Therefore, in light of the level of skill of one of ordinary skill in the art, claim 1 is fully enabled by the present specification.

Reconsideration and withdrawal of the enablement rejection of claims 1, 4, 5, 10, 12, 13 and 15-22 are respectfully requested.

Rejections Under the Obviousness-Type Double Patenting Doctrine

U.S. Patent Application Serial No. 10/621,329

Claims 1, 3-5, 9, 10, 12, 13 and 15-20 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7 and 9-20 of copending U.S. Patent Application Serial No. 10/621,329 ('329). Claims 3 and 9 have been cancelled herein without prejudice or disclaimer, thus obviating the provisional rejection of these claims. This rejection is provisional. Amendments to the claims render this rejection moot. Also, see, M.P.E.P. § 804, I, A, 1.

That is, the Examiner is respectfully requested to follow the procedure that is described in M.P.E.P. § 804(I)(B), and reads as follows:

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent.

Accordingly, the Examiner is respectfully requested to issue a Notice of Allowance in this case and deal with possible double patenting issues in the other applications.

U.S. Patent Application Serial No. 10/621,412

Claims 1, 3-5, 9, 10, 12, 13 and 15-22 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6 and 8-18 of copending US Patent Application No. 10/621,412 ('412). Claims 3 and 9 have been cancelled herein without prejudice or disclaimer, thus obviating the provisional rejection of these claims. This rejection is provisional. Amendments to the claims render this rejection moot. Also, see, M.P.E.P. § 804, I, A, 1.

U.S. Patent Application Serial No. 10/208,336

Claims 1, 3-5, 9, 10, 12, 13 and 15-22 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending US Patent Application No. 10/208,336 ('336). Claims 3 and 9 have been cancelled herein without prejudice or disclaimer, thus obviating the provisional rejection of these claims. This rejection is provisional. Amendments to the claims render this rejection moot. Also, see, M.P.E.P. § 804, I, A, 1.

U.S. Patent Application Serial No. 10/975,469

Claims 1-7 and 10-20 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-26 of copending US

Patent Application No. 10/975,469 ('469). Claims 2, 6, 7, 11 and 14 were previously cancelled in the prior Reply. Claims 3 and 9 have been cancelled herein without prejudice or disclaimer, thus obviating the provisional rejection of these claims. This rejection is provisional. Amendments to the claims render this rejection moot. Also, see, M.P.E.P. § 804, I, A, 1.

CONCLUSION

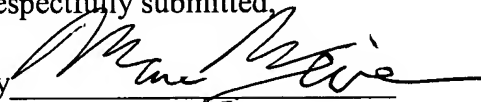
If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By



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Attachments: Declaration of Yumiko TAKESHITA under 37 C.F.R. § 1.132 (5 pages)

